

## **12.0 Living Donation**

The following policies apply to the entire continuum of organ donation from living donors. The process of living donation begins at the time that an individual considers donating an organ, continues through the evaluation of the donor, placement of the organ (whether directed or nondirected), recovery of the organ, and post-donation care and follow-up of the donor.

The following policies apply to member institutions involved in living donation. These policies do not supplant medical judgment or decision-making by transplant professionals or potential or realized living donors.

### **12.1 Definitions** *Reserved.*

### **12.2 Informed Consent of Living Donors** *Reserved.*

### **12.3 Medical Evaluation of Living Donors** *Reserved.*

### **12.4 Independent Donor Advocates** *Reserved.*

## **12.5 Placement of Living Donor Organs**

### **12.5.1 Kidney Placement.**

~~3.5.17~~ **12.5.1.1 Prospective Crossmatching.** A prospective crossmatch is mandatory for all candidates potential living donor recipients. ~~except where clinical circumstances support its omission. The transplant program and its histocompatibility laboratory must have a joint written policy that states when the prospective crossmatch may be omitted.~~ Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3. (Corresponds with OPTN/UNOS Policy 3.5.17—"Prospective Crossmatching")

### **12.5.2 Liver Placement.** *Reserved.*

### **12.5.3 Thoracic Placement.** *Reserved.*

### **12.5.4 Pancreas Placement.** *Reserved.*

### **12.5.5 Intestinal Placement.** *Reserved.*

~~3.3.7~~ **12.6 Center Acceptance and Transplant of Organs from Living Donors.** **Acceptance of Living Donor Organs.** Transplant Centers that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals. (Corresponds with OPTN/UNOS Policy 3.3.7- Center Acceptance and Transplant of Organs from Living Donors)

~~5.0~~ ~~12.7~~ **STANDARDIZED PACKAGING AND TRANSPORTING OF ORGANS AND TISSUE TYPING MATERIALS** **Responsibility for Transport of Living Donor Organs.** The following policies address standardized packaging of live and deceased living donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When an ~~deceased donor~~ organ from a living donor is procured, the ~~Host OPO~~ Transplant Center shall be responsible for ensuring the accuracy of the donor's ABO on the container label and within the donor's documentation. ~~Each OPO~~ The Transplant Center shall establish and implement a procedure for obtaining verification of donor ABO data by an individual other than the person initially performing the labeling and documentation requirements put forth in Policy 5.2

and 5.3. The ~~OPO~~ Transplant Center shall maintain documentation that such separate verification has taken place and make such documentation available for audit. (Corresponds with OPTN/UNOS Policy 5.0—“Standardized Packaging and Transporting of Organs and Tissue Typing Materials”)

Upon receipt of an ~~live or deceased donor~~ organ from a living donor and prior to implantation, the Transplant Center shall be responsible for determining the accuracy and compatibility of the donor and recipient ABO and document this verification in compliance with Policy 3.1.2.

## **5.2**

**12.7.1 Standard Labeling Specifications.** The ~~Host OPO or the~~ Transplant Center shall be responsible for ensuring that the outermost surface of the transport box containing organs and/or tissue typing specimen containers must have a completed standardized external organ container label (provided by the OPTN contractor). Any previous labels on the transport container must be removed prior to labeling the box so that only one label exists. The ~~OPO~~ transplant center shall label each specimen within the package in accordance with policy. The ~~Host OPO~~ transplant center is responsible for ensuring that each tissue or donor organ container that travels outside the recovery facility is labeled appropriately. (Corresponds with OPTN/UNOS Policy 5.2—“Standard Labeling Specifications”)

In the case of ~~deceased or live donor~~ organs from living donors ~~that who~~ remain in the same operating room suite as the intended candidate(s), the ~~Host OPO (if applicable) and~~ Transplant Center must develop, implement, and comply with a procedure to ensure identification of the correct donor organ for the correct recipient. The Transplant Center must document that the correct organ was identified for the correct candidate prior to transplant. Some type of donor organ labeling and documentation must be present in the candidate chart. A “time out” prior to leaving the donor operating room and an additional “time out” upon arrival in the candidate operating room is recommended. Exception: In the case of a single donor organ/organ segment remaining in the same operating room suite as a single intended candidate for a simultaneous transplant, donor organ labeling and “time outs” are not necessary.

In the case of ~~live donor~~ organs from living donors that travel outside the recovery facility, the Transplant Center(s) involved shall be responsible for ensuring that packaging is consistent with the requirements of OPTN Policies 5.2.1 and 5.2.3, and that the outermost surface of the transport box containing the organ must have a completed OPTN/UNOS standardized external organ container label (provided by OPTN Contractor). The recovering Transplant Center shall label each specimen within the package in accordance with OPTN/UNOS policy. The recovering Transplant Center is responsible for ensuring that each container that travels outside the recovery facility is labeled appropriately.

**5.2.1 12.7.2** The ~~Host OPO or the~~ Transplant Center, ~~as applicable~~ is responsible for ensuring that the Donor I.D., Donor ABO type, and a secure label identifying the specific contents (e.g., liver segment, right kidney, ~~heart~~) are attached to the outer bag or rigid container housing the donor organ prior to transport. (Corresponds with OPTN/UNOS Policy 5.2.1)

**5.2.2 12.7.3** Each separate specimen container of tissue typing material must have a secure label with the Donor I.D., Donor ABO type, date and time the sample was procured and the type of tissue. The ~~Host OPO or the~~ Transplant Center, ~~as applicable~~ is responsible for labeling the materials appropriately. (Corresponds with OPTN/UNOS Policy 5.2.2)

**5.2.3 12.7.4** The ~~Host OPO or the~~ Transplant Center, ~~as applicable~~ is responsible for fixing to the transport container the standardized label completed with the Donor I.D., Donor ABO type, a description of the specific contents of the box, the sender’s name and telephone number, and the Organ Center telephone number. A transport container is defined as a corrugated, wax coated disposable box, cooler, or mechanical preservation cassette or machine. (Corresponds with OPTN/UNOS Policy 5.2.3)

**5.3 12.7.5 Packaging.** ABO results must be provided by the ~~Host OPO or the~~ Transplant Center, ~~as applicable~~ in all circumstances during which a donor organ is transported. Properly packaged paperwork containing complete donor information, as described in Policy 2.5.7.1, will

be included with the organ transport container in all instances in which the organ is transported. (Corresponds with OPTN/UNOS Policy 5.3—"Documentation")

- 5.4** **12.7.6 Packaging.** In all circumstances during which a donor organ is transported outside the recovery facility, the ~~Host OPO or the~~ Transplant Center, ~~as applicable~~ is responsible for packaging, labeling, and handling the organ in a manner which ensures arrival without compromise to the organ(s). Proper insulation and temperature controlled packaging including adequate ice or refrigeration shall be used to protect the organs during transport. All packaged organs, using disposable transport boxes, must have a red plastic bio-hazard bag that is water tight secured to allow for safe handling by medical and non-medical personnel during transport. This red bag may be placed between the waxed cardboard box and the insulated material holding the wet ice and the organ. All organs that have been packaged on the donor's back table must be handled using universal precautions. The packaged organs from the donor's surgical back table are to be placed directly into the wet iced shipping container. (Corresponds with OPTN/UNOS Policy 5.4—"Packaging")

**12.8 Reporting Requirements.**

- 7.5.1** **12.8.1** Information pertaining to deceased donor feedback must be submitted to the OPTN within five working days of the procurement date. All living donors must be registered with the OPTN Contractor via the living donor feedback form prior to surgery. (Corresponds with OPTN/UNOS Policy 7.5.1)

- 7.1.5** **12.8.2** The follow-up period for living donors will be a minimum of two years. (Corresponds with OPTN/UNOS Policy 7.1.5)

- 7.3.2** **12.8.3** Living Donor Registration Forms (LDR) must be submitted to the OPTN within 60 days of the form generation date. Recipient transplant centers must complete the LDR form when the donor is discharged from the hospital or by six weeks following the transplant date, whichever is first. The recipient transplant center must submit LDF forms for each living donor at six months, one year and two years from the date of donation. (Corresponds with OPTN/UNOS Policy 7.3.2)

**12.8.4 Submission of Living Donor Death and Organ Failure Data.** Transplant programs must report all instances of living donor deaths and failure of the living donor's native organ function within 72 hours after the program becomes aware of the living donor death or failure of the living donors' native organ function. Live donors' native organ failure is defined as listing for transplant for liver donors, and as transplant, listing for transplant or the need for dialysis in renal donors. Transplant centers must report these incidents through the UNet<sup>SM</sup> Patient Safety System for a period of two years from the date of the donation. The MPSC will review and report all adverse events to the Board. (Corresponds with OPTN/UNOS Policy 7.3.3—"Submission of Living Donor Death and Organ Failure Data")

**12.9 Long-term Care or Support of Living Donors.**

**12.9.1 Follow-up**  
Reserved.

**12.9.2 Insurance.**  
Reserved.

- 3.5.11.6** **12.9.3 Donation Status. Priority on the Waitlist.** A candidate will be assigned 4 points if he or she has donated for transplantation within the United States his or her vital organ or a segment of a vital organ (i.e., kidney, liver segment, lung segment, partial pancreas, small bowel segment). To be assigned 4 points for donation status under Policy 3.5.11.6, the candidate's physician must provide the name of the recipient of the donated organ or organ segment, the recipient's transplant facility and the date of transplant of the donated organ or organ segment, in addition to all other candidate information required to be submitted under policy. Additionally, at the local level of organ distribution only, candidates assigned 4 points for donation status shall be given first priority for kidneys that are not shared mandatorily for 0 HLA mismatching, or for renal/non-renal

organ allocation irrespective of the number of points assigned to the candidate relative to other candidates. When multiple transplant candidates assigned 4 points for donation status are eligible for organ offers under this policy, organs shall be allocated for these candidates according to length of time waiting. (Corresponds with OPTN/UNOS Policy 3.5.11.6—"Donation Status")

**3.5.5.2**     **12.9.4 Exception for Prior Living Donor Organs.** Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations. (Corresponds with OPTN/UNOS Policy 3.5.5.2—"Exception for Prior Living Organ Donors")

***NOTE: New Policy 12.0 (Living Donation) shall be implemented pending distribution of appropriate notice to the membership. (Approved at the June 2009 Board of Directors Meeting.)***